UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Jessica Cagle, Individually and as Mother, General Guardian of M.R., a Minor, Plaintiffs, v. Family Dollar Inc., and Dollar Tree Inc., Defendants.	Court File No. _____ **COMPLAINT** **(JURY TRIAL DEMANDED)**

Plaintiff Jessica Cagle and Plaintiff M.R., pursuant to Fed. R. Civ. P. l 7(c)(l)(A), by and through their undersigned counsel, bring this Complaint for damages against each Defendant Family Dollar Inc., and Dollar Tree Inc., (hereinafter, "Defendant"), in support state the following:

1. This is an action brought on behalf of Plaintiffs, Jessica Cagle (hereinafter, "Plaintiff Mother"), the mother and guardian of M.R. (hereinafter, "Plaintiff M.R."), a minor, arising out of the failure of each Defendant to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter "APAP") and its propensity to cause autism spectrum disorder (hereinafter "ASD") and attention-deficit/hyperactivity disorder ("ADHD") in children. As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to

which they may be legally entitled. Each Defendant entirely failed its duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs' injuries and associated damages.

STATEMENT OF PARTIES

2. At all material times Plaintiffs have been citizens and residents of Clearwater County, Minnesota, and the United States.

3. Each Defendant Family Dollar, Inc. ("Family Dollar") is incorporated in the State of North Carolina, with a principal place of business at 10401 Monroe Road, Matthews, NC 28105-5349. Each Defendant Dollar Tree, Inc. ("Dollar Tree") is incorporated in the State of Virginia, with a principal place of business at 500 Volvo Parkway, Chesapeake, VA 23320. On information and belief, Dollar Tree acquired Family Dollar in or about July 2015.

4. Family Dollar and Dollar Tree is involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter store brand, Acetaminophen (hereinafter, the "APAP Products").

5. Family Dollar and Dollar Tree are individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from each Defendant' design, manufacture, marketing, labeling, distribution, sale, and placement of the defective APAP Products into the market, effectuated directly and indirectly through its agents, servants,

employees, and/or owners, all acting within the course and scope of its agencies, services, employments, and/or ownership.

6. Family Dollar and Dollar Tree are vicariously liable for the acts and/or omissions of its employees and/or agents, who were at all material times acting on behalf of Family Dollar and Dollar Tree, and within the scope of its employment or agency.

VENUE AND JURISDICTION

7. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and Each Defendant.

8. The amount in controversy exceeds $75,000.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 as the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district.

10. Each Defendant has and continues to conduct substantial business in the State of Minnesota and in this District, distributes the APAP in this District, receives substantial compensation and profits from sales of the APAP in this District, and has made material omissions and misrepresentations and breaches of warranties in this District, so as to subject each Defendant to in personam jurisdiction in this District. It was foreseeable at all times that each Defendant could be haled into court in the State of Minnesota for its conduct that caused injuries to citizens of Minnesota, like Plaintiffs in this action. An exercise of in personam jurisdiction by this Court over each Defendant comports fully with due process and does not offend traditional notions of fair play and substantial justice.

11. Each Defendant is registered to transact business in Minnesota.

FACTS COMMON TO ALL COUNTS

APAP Is Marketed as the Safe Pain Reliever for Pregnant Women, but APAP Can Cause Neurodevelopment Disorders in Children, such as ASD and ADHD

12. APAP was initially discovered in the late 1800's.

13. APAP is sold in billions of units annually in North America alone.

14. APAP is widely used by pregnant women to relieve pain during the term of their pregnancy.

15. APAP was introduced to the U.S. market in 1955 as the first aspirin-free pain reliever.

16. APAP has long been marketed as the safest, and the only appropriate, over-the- counter pain relief drug on the market for pregnant women.

17. More than 65% of women in the United States use APAP during pregnancy.

18. Based upon information and belief, a majority of women who use APAP during pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and infection.

19. These pregnant women electively choose to take APAP because each Defendant has marketed APAP as a safe pain reliever for pregnant women.

20. However, increasing experimental and epidemiological research shows that prenatal exposure to APAP alters fetal development, which significantly increases the risks of neurodevelopmental disorders, including but not limited to, autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder.

21. Undisturbed development of the human brain in utero is vital to the health and wellness of a child's development. The human brain is vulnerable and extremely sensitive in utero.

22. During this sensitive time-period in utero, certain chemicals have been found to cause permanent brain injury at low exposure levels.

23. Once ingested by the mother, APAP is known to readily cross the placenta and blood-brain barrier.

24. ASD is a serious neurological and developmental disorder that affects how people interact with others, communicate, learn, and behave.

25. There are three functional levels of ASD, with Level 1 requiring support with activities of daily living, Level 2 requiring substantial support with activities of daily living, and Level 3 requiring very substantial support with activities of daily living.

26. Treatments for ASD include behavioral management therapy, cognitive behavior therapy, joint attention therapies, medications, occupational therapy, physical therapy, social skill training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no cure.

27. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty, hyperactivity, and impulsiveness.

28. ADHD begins in childhood and persists through adulthood. ADHD contributes to low self-esteem, troubled relationships, and difficulty with school, work, and familial relationships.

29. Treatments for ADHD, include, but are not limited to, chronic medication usage and various therapies. Treatment for ADHD lasts a lifetime, as there is no cure.

30. Adults with childhood ADHD are expected to earn $1.25 million less than adults without ADHD over their lifetime, potentially reaching retirement with up to a 75 percent lower net worth.

31. In or around 2018, the Center for Disease Control and Prevention ("CDC") found that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

32. This represents an increase from a prior CDC finding that 1 in 68 U.S. children born in 2002 have ASD, which already represented a more than a 100% increase compared with children born a decade prior.

33. As of 2019, 8.8% of children had been diagnosed with ADHD, or roughly 325,000 children per year.

34. Parental awareness and changes in diagnoses do not account for the rapid rise in these diagnoses of neurodevelopmental disorders.

35. Rather, neurotic exposures, such as prenatal APAP exposure, explain a trending increase in diagnosis.

36. For years, the scientific community has published studies showing that prenatal ingestion of APAP can cause ASD and ADHD.

37. For instance, since 2013, there have been six European birth cohort studies, examining over 70,000 mother-child pairs, showing the association between prenatal use of APAP and ASD and ADHD.

38. At this time, the overall body of scientific evidence shows that prenatal use of APAP can cause ASD and ADHD in the child.

39. During all relevant times herein, each Defendant was engaged in the business of manufacturing and selling the APAP Products in the United States, and the weight of the scientific evidence available showed prenatal exposure to APAP significantly increases the risk of neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to ASD.

40. The scientific evidence regarding the risks of in utero exposure of APAP was available to each Defendant, and each Defendant knew or should have known that prenatal use of APAP can cause ASD.

41. Based on information and belief, each Defendant has concealed the prenatal APAP exposure-neurodevelopmental link from consumers, like Plaintiff Mother, in part by not reporting the link to the FDA, which relies on drug manufacturers to bring new information about a drug to the agency's attention.

42. Moreover, despite knowing that prenatal use of APAP can cause ASD, each Defendant continues to market the APAP Products as the safe pain reliever for pregnant women, making mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

Plaintiff Mother Took APAP while Pregnant, and It Caused ASD and ADHD in Plaintiff Child

43. Plaintiff Mother began using APAP in or around June of 2015, when she was in the early stages of her pregnancy with Plaintiff M.R., through Plaintiff M.R.'s birth.

44. During the entirety of Plaintiff Mother's pregnancy, she took APAP, seven or more times a week, to treat back pain and as pain relief.

45. These were pains Plaintiff Mother associated with her pregnancy.

46. Plaintiff Mother electively took the APAP while pregnant.

47. Plaintiff Mother believed it was safe for her to take the APAP during her pregnancy.

48. Had Plaintiff Mother known of the risk of taking APAP while pregnant, specifically that it could cause ASD in her child, Plaintiff M.R., she would not have taken the APAP.

49. Plaintiff M.R. was born on April 11, 2016.

50. Plaintiff Mother started noticing issues with Plaintiff M.R. before she started school, as she was delayed in development.

51. Plaintiff M.R. was diagnosed with autism in August, 2019.

52. Plaintiff M.R. is enrolled in special services at her school and has had an individualized education plan for autism.

53. Plaintiff M.R., exhibits stemming behaviors and other repetitive movements.

54. Plaintiff M.R. will continue to require intensive assistance and therapy.

55. These issues have a huge impact on Plaintiff Mother and Plaintiff M.R.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

56. Due to each Defendant's acts of fraudulent concealment, each Defendant is estopped from relying on any statutes of limitations or repose. Such acts include each Defendant's intentional concealment from Plaintiff Mother and the general public that APAP is defective when there is prenatal exposure, while continuing to market the APAP with the adverse effects described in this Complaint.

57. Given each Defendant's affirmative actions of concealment by failing to disclose information about the defects known to them but not the public-information over which each Defendant had exclusive control, and because Plaintiff Mother could not reasonably have known that the APAP was defective, each Defendant is estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted in this Complaint.

COUNT I: STRICT LIABILITY - FAILURE TO WARN

58. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

59. At the time of Plaintiffs' injuries, the APAP was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff Mother, because they lacked an adequate warning.

60. At all relevant times, each Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and

promoting the APAP, which was defective and unreasonably dangerous to consumers, including Plaintiff Mother, because they did not contain adequate warnings or instructions concerning the dangerous characteristics of ingesting APAP during pregnancy. These actions were under the ultimate control and supervision of each Defendant. At all relevant times, each Defendant registered, researched, manufactured, distributed, marketed, labeled, promoted, and sold the APAP within this District and aimed the marketing at the ultimate consumer. Each Defendant was at all relevant times involved in the retail and promotion of the APAP marketed and sold in this District.

61. Each Defendant had a duty to warn of the risks associated with the use of the APAP.

62. The APAP ingested by Plaintiff Mother during her pregnancies was in the same or substantially similar condition as it was when it left possession of each Defendant.

63. Each Defendant expected and intended the APAP to reach users such as Plaintiff Mother in the condition in which the APAP was sold.

64. Plaintiff Mother did not materially alter the APAP prior to ingestion.

65. Plaintiff Mother ingested the APAP as indicated on the APAP labels.

66. Plaintiff Mother was unaware of the defects and dangers of the APAP and was unaware that prenatal exposure increases the risk of brain and behavioral development of children in utero.

67. The labels on the APAP to consumers lack any warning specific to pregnant women. The information that each Defendant did provide or communicate failed to contain

relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff Mother to utilize the products safely and with adequate protection or decide to not ingest the APAP at all.

68. This alleged failure to warn is not limited to the information contained on the APAP's labeling. Each Defendant was able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with APAP through other non-labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public information sources. But each Defendant did not disclose these known risks through any medium.

69. At all relevant times, each Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the APAP; provide proper warnings for the APAP; and take such steps as necessary to ensure the APAP did not cause users and consumers, and their children, to suffer from unreasonable and dangerous risks. Each Defendant had a continuing duty to warn Plaintiff Mother of dangers associated with APAP. Each Defendant, as manufacturer, seller, and/or distributor of pharmaceutical medication, is held to the knowledge of an expert in the field.

70. At the time of manufacture, each Defendant could have provided the warnings or instructions regarding the full and complete risks of the APAP because each Defendant knew or should have known of the unreasonable risks of ASD and ADHD associated with prenatal exposure to and/or the use of such products.

71. At all relevant times, each Defendant failed and deliberately refused to investigate, study, test, or minimize the dangers to consumers of the APAP and to those who would foreseeably use or be harmed by the APAP, including Plaintiffs.

72. Each Defendant failed to adequately warn consumers, like Plaintiff Mother, about the significant increased risk of neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to ASD and ADHD.

73. Each Defendant failed to adequately inform reasonably foreseeable consumers, like Plaintiff Mother, of the proper usage of the APAP. Even though Each Defendant knew or should have known that APAP posed a grave risk of harm to Plaintiff Child, each Defendant failed to exercise reasonable care to warn of the dangerous risks associated with use and prenatal exposure.

74. Plaintiff Mother was exposed to the APAP without knowledge of its dangerous characteristics.

75. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the APAP while using it for its intended or reasonably foreseeable purposes, without knowledge of its dangerous characteristics.

76. Plaintiff Mother could not have reasonably discovered the defects and risks associated with the APAP prior to or at the time of Plaintiff consuming APAP. Plaintiff Mother relied upon the skill, superior knowledge, and judgment of each Defendant to know about and disclose serious health risks associated with using the APAP.

77. If Plaintiff Mother had been properly warned of the defects, dangers, and risks associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest the APAP at all.

78. Each Defendant is liable to Plaintiffs for injuries caused by each Defendant's negligent or willful failure, as described above, to provide adequate warnings or other relevant information and data regarding the appropriate use of the APAP and the risks associated with the use of APAP.

79. As a direct and proximate result of each Defendant placing defective APAP into the stream of commerce, and Plaintiff Mother's ingestion of the APAP during pregnancy, Plaintiff M.R. was exposed to APAP prenatally, causing him to develop ASD and ADHD.

80. As a direct and proximate result of each Defendant placing defective APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT II: NEGLIGENCE

81. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

82. Although each Defendant had a duty to use reasonable care in testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing written instructions and warnings for the APAP, each Defendant failed to do so.

83. Each Defendant, directly or indirectly, caused the APAP to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all relevant times, each Defendant was registered, researched, manufactured, distributed, marketed, promoted, and sold the APAP within this district and aimed at a consumer market within this district.

84. Each Defendant knew, or in the exercise of reasonable care should have known, that the APAP was defectively and unreasonably designed and/or manufactured, and/or marketed, and was unreasonably dangerous and likely to injure persons that were prenatally exposed to them. Each Defendant knew or should have known that Plaintiff Mother was unaware of the dangers and defects inherent in the APAP when she was ingesting them during her pregnancy with Plaintiff M.R.

85. At all relevant times, each Defendant had a duty to exercise reasonable care in the marketing, advertisement, promotion, and sale of the APAP. Each Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using APAP during pregnancy and appropriate, complete, and accurate warnings concerning the potential adverse effects of APAP and, in particular, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

86. At all relevant times, each Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of APAP ingestion while pregnant

and, specifically, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

87. Each Defendant failed to provide any kind of warning to pregnant consumers, like Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

88. Accordingly, at all relevant times, each Defendant knew or, in the exercise of reasonable care, should have known that use of the APAP could cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiffs.

89. As such, each Defendant breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, labeling, supply, promotion, advertisement, packaging, sale, and distribution of the APAP, in that each Defendant manufactured and produced defective APAP, which causes a significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP; knew or had reason to know of the defects inherent in the APAP; knew or had reason to know that a user's or consumer's use of the APAP created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

90. Each Defendant had a duty to disclose the truth about the risks associated with APAP in its promotional efforts outside of the context of labeling. Each Defendant was negligent in their promotion of APAP outside of the labeling context by failing to

disclose material risk information as part of its promotion and marketing of the APAP, including through the internet, television, and print advertisements.

91. Despite each Defendant's ability and means to investigate, study, and test the APAP and to provide adequate warnings, each Defendant failed to do so. Indeed, each Defendant wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of APAP.

92. Each Defendant's negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the APAP while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of APAP and the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and, consequently, the risk of serious harm associated with human use of APAP during pregnancy;

b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the APAP was safe for its intended consumer use and unborn children;

c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons each Defendant could reasonably foresee would use the APAP;

d. Failing to disclose to Plaintiff Mother, users, consumers, and the general public that use of APAP during pregnancy presents severe risks of neurodevelopmental disorders in children exposed to APAP prenatally;

e. Failing to warn Plaintiff Mother, users, consumers, and the general public that the APAP's risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff Mother and other users and/or consumers;

f. Representing that the APAP was safe for their intended purposes for pregnant women when, in fact, each Defendant knew or should have known the APAP was not safe for their intended purposes;

g. Declining to make or propose any changes to the APAP's labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women;

h. Advertising, marketing, and recommending the use of the APAP, while concealing and failing to disclose or warn of the dangers known by each Defendant to be caused by the use of or exposure to APAP;

i. Continuing to disseminate information to its consumers and the general public, which indicates or implies that the APAP are not unsafe for pregnant consumer use; and

j. Continuing the manufacture and sale of the APAP with the knowledge that the APAP was unreasonably unsafe and dangerous.

93. Each Defendant knew and/or should have known that it was foreseeable that children such as Plaintiff M.R. would suffer injuries as a result of each Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the APAP to consumers, like Plaintiff Mother.

94. Plaintiff Mother did not know the nature and extent of the injuries that could result in her child from the intended use of and/or exposure to APAP prenatally.

95. Each Defendant's negligence was the proximate cause of Plaintiffs' injuries, i.e., absent each Defendant's negligence, Plaintiff S.S would not have developed ASD.

96. As a direct and proximate result of each Defendant placing the defective APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT III: BREACH OF EXPRESS WARRANTY

97. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

98. At all material times, each Defendant manufactured, marketed, sold, distributed, and otherwise placed into the stream of commerce the APAP. These actions were under the ultimate control and supervision of each Defendant.

99. In advertising, marketing, and promoting the APAP to consumers, like Plaintiff Mother, each Defendant expressly warranted that the APAP was safe for use and

reasonably fit for their intended purposes. In advertising, marketing, and otherwise promoting the APAP, each Defendant intended for pregnant consumers to rely upon its representations regarding safety and fitness, in an effort to induce them to purchase and consume the APAP during pregnancy to relieve pain.

100. Each Defendant expressly warranted to Plaintiff Mother and pregnant consumers that the APAP was safe for ingestion during pregnancy.

101. Each Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of the APAP, including a duty to:

a. ensure that the APAP did not cause users and their unborn children unreasonably dangerous side effects;

b. warn of dangerous and potentially incurable side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to APAP during pregnancy, when making representations to users, consumers, and the general public, including Plaintiff Mother.

102. Each Defendant had the ability to properly disclose the risks associated with APAP usage during pregnancy through multiple channels, not just labeling.

103. At all relevant times, each Defendant expressly represented and warranted to the purchasers of the APAP, by and through statements made by each Defendant in labels, publications, brochures, and other written materials intended for consumers and the general

public, that the APAP was safe to human health and the environment, effective, fit, and proper for their intended use. Each Defendant advertised, labeled, marketed, and promoted the APAP, representing the quality to consumers and the public in such a way as to induce their purchases or use, thereby making an express warranty that the APAP would conform to the representations.

104. The representations about the APAP, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

105. Each Defendant breached express representations and warranties made to Plaintiff Mother, with respect to the APAP, including the following:

a. Each Defendant represented through its labeling, advertising, and marketing materials that the APAP was safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of APAP and by expressly limiting the risks associated with use within its warnings and labels; and

b. Each Defendant represented that the APAP was safe for use and intentionally concealed information that demonstrated that APAP carries the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and that the APAP, therefore, was not safer than alternatives available on the market.

106. Plaintiff Mother detrimentally relied on the express warranties and representations of each Defendant concerning the safety and/or risk profile of APAP in deciding to purchase the APAP. Plaintiff Mother reasonably relied upon each Defendant to disclose known defects, risks, dangers, and side effects of APAP. Plaintiff Mother would not have purchased or used the APAP had each Defendant properly disclosed the risks associated with the APAP, either through advertising, labeling, or any other form of disclosure.

107. Plaintiff Mother had no knowledge of the falsity or incompleteness of each Defendant's statements and representations concerning the APAP.

108. Plaintiff Mother used and/or was exposed to APAP as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by each Defendant.

109. Had the warnings, labels, advertisements, or promotional material for the APAP accurately and adequately set forth the true risks associated with the use of such Products, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the APAP was safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

110. As a direct and proximate result of each Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT IV: BREACH OF IMPLIED WARRANTY

111. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

112. At all material times, each Defendant manufactured, marketed, sold, distributed, and otherwise placed the APAP into the stream of commerce.

113. At all material times, each Defendant intended for the APAP to be consumed and ingested by pregnant women, like Plaintiff Mother; and each Defendant impliedly warranted that the APAP and its component parts were of merchantable quality, safe, fit for such use, and adequately tested.

114. Each Defendant was aware that consumers, including Plaintiff Mother, would consume and ingest the APAP as directed by the Products' labels and promotional materials. Therefore, Plaintiff Mother was a foreseeable user of the APAP.

115. But each Defendant failed to disclose that APAP has dangerous propensities when used as intended and that use of the APAP carries an increased risk of developing severe injuries, including Plaintiff M.R.'s injuries.

116. The APAP was expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which they were manufactured and sold by each Defendant.

117. Plaintiff Mother was an intended beneficiary of the implied warranties made by each Defendant to purchasers of the APAP.

118. In reliance upon each Defendant's implied warranties, Plaintiff Mother used the APAP as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by each Defendant.

119. Each Defendant breached its implied warranties to Plaintiffs in that the APAP was not of merchantable quality, nor were they safe or fit for their intended use or adequately tested.

120. The harm caused by the APAP far outweighed their benefit, rendering the APAP more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

121. As a direct and proximate result of each Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS

122. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

123. Plaintiff Mother purchased and used the APAP for primarily personal use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of each Defendant's actions in violation of the consumer protection laws.

124. Had each Defendant not engaged in the deceptive conduct described in this Complaint, Plaintiff Mother would not have purchased and/or paid for the APAP, and Plaintiffs would not have incurred related injury medical costs.

125. Each Defendant engaged in wrongful conduct while at the same time obtaining under false pretenses moneys from Plaintiff Mother for the APAP. Those moneys would not have been paid had each Defendant not engaged in unfair and deceptive conduct.

126. Each Defendant engaged in the following unfair methods of competition or deceptive acts or practices, which are proscribed by law:

a. representing that goods or services have characteristics, ingredients, uses, benefits, or qualities they do not have;

b. advertising goods or services with the intent not to sell them as advertised; and

c. engaging in fraudulent or deceptive conduct creating a likelihood of confusion or misunderstanding.

127. Plaintiffs were injured by the cumulative nature of each Defendant's conduct. The cumulative effect, directed at patients, physicians, and consumers, was to create demand for and sell the APAP. Each aspect of each Defendant's conduct combined to artificially create sales of the APAP.

128. Each Defendant had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the APAP.

129. Each Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers, including Plaintiff Mother, constitute unfair and

deceptive acts and trade practices in violation of the federal and state consumer protection statutes listed below.

130. Each Defendant's actions, as complained of in this Complaint, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of the federal and state consumer protection statutes listed below.

131. Each Defendant has engaged in unfair competition, or unfair or deceptive acts or trade practices, or has made false representations under the following statutes:

- 15 U.S.C. §§ 2301-12 (1982); and
- Minnesota Statute§§ 325D.43, *et seq* (Uniform Deceptive Trade Practices)
- Minnesota Statute§§ 325D.09, *et seq* (Unlawful Trade Practices)
- Minnesota Statute§ 325F.67 (False Statement in Advertisement)
- Minnesota Statute§§ 325F.68, *et seq* (Prevention of Consumer Fraud)

132. To protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, each Defendant, as the supplier, manufacturer, advertiser, and seller, are subject to liability under the above legislation enacted against unfair, deceptive, fraudulent, and unconscionable consumer sales practices. By knowingly and falsely representing that the APAP was fit to be used for the purposes for which they were intended-when in fact they were defective and dangerous, and by other acts alleged, each Defendant violated the above statutes, enacted to protect

consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

133. Each Defendant's actions and omissions are uncured or incurable, deceptive acts under the above legislation.

134. Each Defendant had actual knowledge of the defective and dangerous conditions of the APAP but failed to take any action to cure such defective and dangerous conditions.

135. Plaintiff Mother relied upon each Defendant's misrepresentations and omissions in determining which APAP (if any) to ingest.

136. Each Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers constituted unfair and deceptive acts and practices.

137. By reason of the unlawful acts in which each Defendant engaged, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

138. As a direct and proximate result of each Defendant's violations of the above-listed legislation, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VI: NEGLIGENT MISREPRESENTATION

139. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

140. Each Defendant had a duty to accurately and truthfully represent to consumers, including Plaintiff Mother, and the public that the APAP had not been

adequately tested and found to be a safe and effective treatment for pregnant women. Each Defendant breached that duty as its representations were false.

141. Each Defendant failed to exercise ordinary care in the representations concerning the APAP while each Defendant was involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because each Defendant negligently misrepresented the APAP's high risk of unreasonable and dangerous adverse side effects.

142. Each Defendant also breached its duty in representing to Plaintiff Mother that the APAP had no serious side effects when ingested during pregnancy.

143. As a foreseeable, direct, and proximate result of each Defendant's negligent misrepresentations, each Defendant knew or had reason to know that the APAP had been insufficiently tested or had not been tested at all; and that they lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk, of adverse side effects. Those side effects include neurodevelopmental disorders in children, such as ASD and ADI-ID.

144. As a direct and proximate result of each Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

WHEREFORE, Plaintiffs demand judgment against each Defendant. Plaintiffs also request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against each Defendant and pray for the following relief in accordance with applicable law and equity:

A. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

B. Restitution and disgorgement of each Defendant’s profits;

C. Reasonable attorneys' fees as provided by law;

D. Past and future costs of all proceedings

E. All ascertainable economic damages;

F. Prejudgment interest on all damages as allowed by law; and

G. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs request a jury trial as to all issues triable by a jury.

Dated: August 2, 2022

Respectfully submitted,

s/Daniel E. Gustafson

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